

141-400

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT OPERATION

In re Application of:

Xie et al.

Serial No.: 10/822,627

Group Art Unit: --

Filed: April 12, 2004

Examiner: --

For: **CONTROLLED RELEASE OPIOD ANALGESIC FORMULATION**

New York, NY 10036
June 21, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

The following statement of relevance is submitted with the accompanying
Form PTO/SB/08A.

Document
Designation

Relevance

AA
U.S.P. 4,235,870

Relates to a slow release pharmaceutical composition.

AB
U.S.P. 4,327,725

Relates to an osmotic device with hydrogel driving member.

AC
U.S.P. 4,443,428

Relates to an extended action controlled release composition.

I hereby certify that this correspondence is being deposited with the
United States Postal Service as first class mail in an envelope
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Commissioner for Patents
P.O. Box 1450

Alexandria, VA 22313-1450

on June 21, 2004


Martin P. Endres, Reg. No. 35,498

<u>Document Designation</u>	<u>Relevance</u>
AD U.S.P. 4,569,937	Relates to an analgesic mixture of oxycodone and ibuprofen.
AE U.S.P. 4,581,225	Relates to a sustained release intranasal formulation and method of use thereof.
AF U.S.P. 4,612,008	Relates to an osmotic device with dual thermodynamic activity.
AG U.S.P. 4,626,539	Relates to a transdermal delivery of opioids.
AH U.S.P. 4,783,337	Relates to an osmotic system comprising plurality of members for dispensing drug.
AI U.S.P. 4,861,598	Relates to a controlled release base for pharmaceuticals.
AJ U.S.P. 4,879,297	Relates to fatty acids and their small chain esters as penetration enhancers in aqueous systems.
AK U.S.P. 4,970,075	Relates to a controlled release base for pharmaceuticals.
AL U.S.P. 5,082,668	Relates to a controlled-release system for pharmaceuticals with a constant pushing source.
AM U.S.P. 5,266,331	Relates to a controlled release oxycodone composition.
AN U.S.P. 5,478,577	Relates to a method of treating pain by administering a 24 hour oral opioid formulation that exhibits a rapid rate of initial rise of plasma drug level.
AO U.S.P. 5,508,042	Relates to a controlled release oxycodone composition.
AP U.S.P. 5,549,912	Relates to a controlled release oxycodone composition.
AQ U.S.P. 5,656,295	Relates to a controlled release oxycodone composition.
AR U.S.P. 5,672,360	Relates to a method of treating pain by administering a 24 hour oral opioid formulation.

BA
EP 0 698 389

Relates to a controlled release matrix for pharmaceuticals.

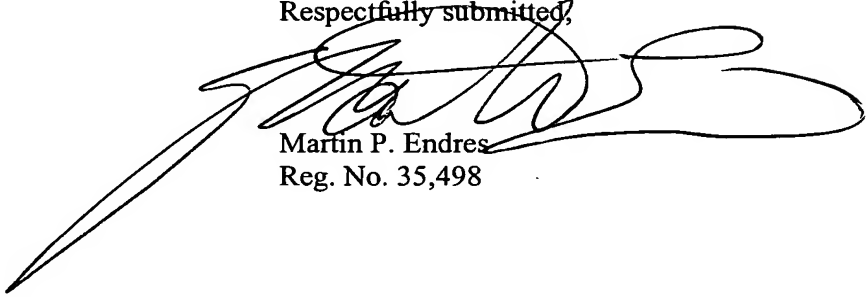
CA
55th Edition 2001
Physicians' Desk Reference
pgs. 2697-2701

Relates to oxycodone formulation.

In accordance with current Patent and Trademark Office practice no copy of the above listed United States Patents are filed herewith as well as copies of abstracts in English. Full text copies of all non-United States Patent prior art are enclosed herewith. It is respectfully requested that this art be considered by the Examiner in the above-entitled application and made of record therein.

It is respectfully requested that this art be considered by the Examiner in the above-entitled application and made of record therein. It is believed that no fee is required for submission of this Information Disclosure Statement under 37 C.F.R. §1.97(b). However, if a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 08-1540.

Respectfully submitted,



Martin P. Endres
Reg. No. 35,498

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/822,627
Filing Date	April 12, 2004
First Named Inventor	Jianbo Xie
Art Unit	
Examiner Name	
Attorney Docket Number	141-400

Sheet 1 of 2

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA	US- 4,235,870	11-25-1980	Leslie	
	AB	US- 4,327,725	05-04-1982	Cortese et al.	
	AC	US- 4,443,428	04-17-1984	Oshlack et al.	
	AD	US- 4,569,937	02-11-1986	Baker et al.	
	AE	US- 4,581,225	04-08-1986	Su et al.	
	AF	US- 4,612,008	09-16-1986	Wong et al.	
	AG	US- 4,626,539	12-02-1986	Aungst et al.	
	AH	US- 4,783,337	11-08-1988	Wong et al.	
	AI	US- 4,861,598	08-29-1989	Oshlack	
	AJ	US- 4,879,297	11-07-1989	Mahjour et al.	
	AK	US- 4,970,075	11-13-1990	Oshlack	
	AL	US- 5,082,668	01-21-1992	Wong et al.	
	AM	US- 5,266,331	11-30-1993	Oshlack et al.	
	AN	US- 5,478,577	12-26-1995	Sackler et al.	
	AO	US- 5,508,042	04-16-1996	Oshlack et al.	
	AP	US- 5,549,912	08-27-1996	Oshlack et al.	
	AQ	US- 5,656,295	08-12-1997	Oshlack et al.	
	AR	US- 5,672,360	09-30-1997	Sackler et al.	
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	BA	EP 0 698 389 A1	02-28-1996	Krishnamurthy		

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Sheet	2	of	2	Application Number	10/822,627
				Filing Date	April 12, 2004
				First Named Inventor	Jianbo Xie
				Art Unit	
				Examiner Name	
				Attorney Docket Number	141-400

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CA	55th Edition 2001, Physician's Desk Reference pgs. 2697-2701.	

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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